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10/573,500	08/18/2008	Stefan Golz	004974.01112	5423

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EXAMINER	
RAGHU, GANAPATHIRAM	
ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,500	GOLZ ET AL.	
	Examiner	Art Unit	
	GANAPATHIRAMA RAGHU	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *43-75* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *SEQ ALIGN*.

Detailed Action

Claims 43-75 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I: Claims 43, 45-47, 72 and 73, drawn to a nucleic acid sequence of SEQ ID NO: 1 encoding a polypeptide of SEQ ID NO: 2, vectors, host cells, the method of making said polypeptide and pharmaceutical compositions comprising said polynucleotide.

Note: Claims 45-47 are included in Group I, although claims recite to depend from claim 52, however, claim 52 is directed to a method and not the product-polynucleotide.

Group II: Claims 44 and 74, drawn to a purified polypeptide comprising an amino acid sequence of SEQ ID NO: 2 having MGAT-X1 activity and pharmaceutical compositions comprising said polypeptide.

Group III: Claims 48-50, drawn to method of detection of nucleic acid molecule encoding a MGAT-X1, said nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1 and encoding a protein comprising the amino acid sequence of SEQ ID NO: 2.

Group IV: Claim 51, drawn to method a method of detection of a polypeptide, said polypeptide comprising the amino acid sequence of SEQ ID NO: 2.

Group V: Claims 52-60, drawn to method for screening regulators of the activity of MGAT-X1, said method contacting a test compound with the polypeptide comprising a an amino acid sequence of SEQ ID NO: 2.

Group VI: Claims 61-64, drawn to method for screening regulators of the activity of MGAT-X1, said method comprising measuring the activity of a polypeptide at certain concentration of a test compound or in the absence of a test compound contacting a test compound wherein the polypeptide comprising a an amino acid sequence of SEQ ID NO: 2.

Group VII: Claims 65-70, drawn to method for screening regulators of the activity of MGAT-X1, said method contacting a test compound with the polynucleotide comprising a nucleotide sequence of SEQ ID NO: 1 and encoding a polypeptide comprising an amino acid sequence of SEQ ID NO: 2.

Group VIII: Claim 71, drawn to method diagnosing MGAT-X1 related disease in a diseased mammal, comprising measuring the amount of nucleic acid molecule in a sample wherein the nucleic acid molecule is selected from the group consisting of a nucleotide sequence of SEQ ID NO: 1 and encoding a polypeptide comprising an amino acid sequence of SEQ ID NO: 2.

Group IX: Claim 75 in part, drawn to a pharmaceutical composition comprising a regulator of MGAT-X1 selected from the group consisting of an RNA molecule.

Group X: Claim 75 in part, drawn to a pharmaceutical composition comprising a regulator of MGAT-X1 selected from the group consisting of an antisense oligonucleotide.

Group XI: Claim 75 in part, drawn to a pharmaceutical composition comprising a regulator of MGAT-X1 selected from the group consisting of an antibody.

Group XII: Claim 75 in part, drawn to a pharmaceutical composition comprising a regulator of MGAT-X1 selected from the group consisting of a ribozyme.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following categories:

1) A product and a process specially adapted for the manufacture of said product or

2) A product and process of use of said product; or

3) A product, a process specially adapted for the manufacture of said product and a use of said product; or

4) A process and an apparatus or means specifically adapted for carrying out the said process; or

5) A product, a process specially adapted for the manufacture of said product and an apparatus or means specifically designed for carrying out the said process.

37 CFR 1.475(c) states: If an application contains more or less than one of the combination of categories of in an invention set forth in paragraph (b) of this section, unity of invention might not be present.

In addition, the PCT does not provide for multiple products or methods within single application, therefore, unity of invention is lacking with regard to Groups I-XII; see 37 CFR 1.475. 37 CFR 1.475 (d) also states: If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) 1.47(c).

37 CFR 1.475(e) further states; the determination whether a group of invention is so linked as to form a single inventive concept shall be without regard to whether the inventions are claimed in separate claims or as alternative within a single claim.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The polynucleotides of Groups I and the polypeptides of Groups II do not share a corresponding special technical feature even though the polynucleotide encodes the polypeptide, because the prior art clearly teaches isolation and purification of polynucleotides encoding the polypeptides having enzyme diacylglycerol acyltransferase activity, said reference polynucleotide having 98% best local similarity to SEQ ID NO: 1 of the instant invention and the encoded polypeptide having 99.4% best local similarity to SEQ ID NO: 2 of the

instant invention (see provided sequence alignment; WO 2003053363 Gimeno et al.,). Therefore, the only shared technical feature of these claims, polynucleotides encoding polypeptides having MGAT-X1activity does not constitute a special technical feature as defined in PCT Rule 13.2, as it is not a feature which defines a contribution of the claimed invention makes over the prior art. The methods of Groups III-VIII do not share any technical feature with Groups I-II and do not have unity of invention with Groups I-II as Groups I-II already includes a method of use of the DNA which comprises unrelated steps to the methods of Groups III-VIII and 37 CFR 1.475 does not provide for the inclusion of multiple methods of use within the main invention.

Searching more than one of Groups I-XII would represent a burden on the Office for the following reasons. Because the products used in the method of Groups III-VIII and the products of Groups I, II, IX-XII do not share a special structural and functional feature, a search for any one said product would not encompass a search for any other said products used in the method of Group III-VIII. Thus, the search for more than one of Groups I-XII would be a burden on the Office. A search of any one of the products of Groups I, II, IX-XII would not encompass a search of any of the methods of Groups III-VIII, or vice versa, because said methods are not the only methods of making or using said products. These inventions lack Unity of Invention for the reasons given above. Furthermore, each invention has acquired a separate status in the art due to their recognized divergent subject matter and, thus, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder of restricted inventions

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. **Failure**

to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached between 8 am-4: 30 pm EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Ganapathirama Raghu/
Patent Examiner
Art Unit 1652